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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,331

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Orit Kollet

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EXAMINER

KIM, TAEYOON

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

10/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,331	Applicant(s) KOLLET ET AL.	
	Examiner TAEYOON KIM	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-74 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-74 are pending.

Upon further inspection, the examiner has determined that new restriction is necessary. The following requirement for restriction and election of species should be substituted for the requirement mailed 7/17/2008. Any inconvenience is regretted.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-10 and 36-46, drawn to a method of making stem cells sensitive to a chemoattractant by exposing stem cells to HGF.

Group II, claims 11-18, drawn to a method of using stem cells sensitive to a chemoattractant by exposing stem cells to HGF.

Group III, claims 19-26, drawn to a method of administering HGF to a subject in need thereof.

Group IV, claims 47-55 drawn to stem cells and cell lines expressing HGF.

Group V, claims 56-60 drawn to a cell culture comprising stem cells and feeder cells expressing HGF.

Group VI, claims 61-70, drawn to a method of upregulating endogenous HGF in stem cells.

Group VII, claims 71 and 72, drawn to a method of administering HGF.

Group VIII, claims 73 and 74, drawn to a HGF composition.

It is noted that claims 27-35 are drawn to a use of HGF. Since the use claims are considered as non-statutory and thus, are not included in the current restriction requirement.

(a) An international or national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those invention involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) a product and a process specially adapted for the manufacture of said product; or
- (2) a product and a process of use of said product; or
- (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) a process and an apparatus or means specifically designed for carrying out said process; or

(5) a product, a process specially adapted for the manufacture of the said product and an apparatus or means specifically designed for carrying out said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

There are multiple products, processes of manufacture or uses are claimed in the current invention. As indicated above, the category first mentioned in the claims of the application (Groups I, II and V) is considered as the main invention in the claims. The groups of invention fall within category (2), a product and a method of use of that product.

In addition to the requirement that a group of inventions must belong to one of the specific categories provided by PCT Rule 13.2, the inventions in the category, such as a composition and a method of use of the composition, must have a special technical feature that unites them. See Patent Rules 1.475, where a special technical feature is a contribution over the prior art.

The inventions listed as Groups I, II and V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the

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same or corresponding special technical features for the following reasons: The inventions of Groups I, II and V are all related to “stem cells exposed to HGF”.

However, this concept cannot be considered as the “single general inventive concept” required by Rule 13 PCT because it is neither novel nor inventive. The prior art teaches uses of HGF as a colonization composition promoting engraftment (WO/2002/50263; IDS ref.) as a hematopoietic augmenting factor (EP 0550769; IDS ref.) and HGF is used as a “mobilizer” of hematopoietic progenitors as a source of stem cells for bone marrow transplant (US 5968501; IDS ref.). Based on the prior art listed above, the unity of Groups I, II and V inventions is lacking.

The expression “special technical feature” refers to those features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Thus, a feature found in the prior art cannot be considered to be a special technical feature.

A single general inventive concept must link the claims in the various categories, and in this connection the wording should be carefully noted. The link between a product and process of making it required for inventive unity is that the process must be “specially adapted for the manufacture of” the product. Similarly, an apparatus or means claimed must be “specifically designed for” carrying out the process of using the apparatus. In combinations of product and process claims, the emphasis is on, and the essence of the invention should primarily reside in, the product, whereas in combinations of apparatus and process claims, the emphasis is on, and the invention should primarily reside in, the process. See Examples in Chapter 10 of the International

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Search and Preliminary Examination Guidelines (which can be obtained from WIPO's web site (www.wipo.int/pct/en/texts/gdlines.htm) and M.P.E.P. 1850, section III (A).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 4:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Examiner, Art Unit 1651